

REMARKS

Claims 2 and 6 have been canceled due to their subject matter being written directly into the language of their parent Claims 1 and 5. Claim 1 has been amended to include the limitations of Claim 2. Claim 5 has been modified to include the limitations of Claim 6. Claims 7 and 8 have been modified by changing their dependence onto Claim 5. Claims 1, 3-5 and 7-9 are under consideration at this time. Claims 10-15 have been withdrawn from consideration as being drawn to a nonelected invention.

The Examiner has objected to the specification because of the certificate of mailing stamp on page 1. Applicants do not understand what is wanted here. Section 512 of the Manual of Patent Examining Procedure related to Certificate of Mailing in the section entitled "Procedure By Applicant" states in paragraph B that "When possible, the certification should appear on a portion of the paper being submitted." Applicants have never seen this rejection before and request that it be dropped or clarified, and the basis of what is required be set forth.

Claims 2-4 and 6-8 have been rejected under 35 U.S.C. 112, first paragraph, as not being enabled by the specification. The Examiner has required that the disclosed and claimed cultures be deposited.

In response, the strains of *Flavobacterium columnare* NRRL-30303 and NRRL-30304, were deposited under the Budapest Treaty in the Agricultural Research Service Culture Collection (1815 N. University, Peoria, IL 61604-3999) on June 20, 2000 (prior to the filing date of the instant application), and were assigned the above-mentioned deposit accession numbers. Again, see the enclosed Deposit Receipt Form from the International Depository acknowledging receipt of the deposits.

In addition, Applicants' representative, Joseph A. Lipovsky, hereby states that the deposit of the disclosed and claimed probiotic compositions NRRL-30303 and NRRL-30304 will comply with the requirements of 37 CFR 1.801-1.809, and specifically that:

- (1) all restrictions on availability of the deposits will be irrevocably removed upon the granting of the patent, and
- (2) the deposits will be replaced if they should become non-viable.

Claims 5-9 are rejected under 35 U.S.C. 112, first paragraph because it is the Examiner's position that the specification, while being enabling for an attenuated strain of a bacterium treating catfish against bacterial disease, does not reasonably provide enablement for a vaccine. With the instant amendment

Applicants have amended the scope of Claim 5 to more clearly reflect the invention and address the issues raised.

The definition of a "vaccine" by Dorlands Medical dictionary is not seen to be an issue in the present case because Applicants have supplied their own definition of "vaccine" at the time the case was filed. On page 5, paragraph 10 of the application Applicants defined vaccine as follows:

"Vaccine is defined herein in its broad sense to refer to any type of biological agent in an administrable form capable of stimulating a protective immune response in an animal inoculated with the vaccine. For purposes of this invention, the vaccine may comprise one or more live attenuated mutants of *F. columnare* having the characteristic of rifampicin-resistance."

Applicants are allowed to be their own lexicographer as long as their definition does not fly in the face of what is known in the art. The reliance on Dorlands is thus seen as improper for the present situation as the term "vaccine" was defined by the Applicants within the specification as filed.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention. Specifically, the Examiner states it is not clear what Applicants intend by the recitation of the limitations "effective for eliciting an immune response in fish

which is protective against infection" in Claim 1, and "an effective immunization dosage the attenuated strain of" in Claim 5.

Applicants have amended the instant application to limit the scope of the claims to the strains set forth in what was originally Claim 2. The present limitation makes it clear what the elicited immune response is protective against. This language also reads over into Claim 5 based on its dependence on Claim 1, further the claim has been modified to correct this issue. If for some reason Applicants have missed the focus of the issue, they would appreciate clarification and suggested language.

Claims 1, 5 and 9 are rejected by the Examiner under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wolf-Watz et al. (U.S. 5,284,653). The Examiner includes the note that the claims are drawn to a composition comprising a *Flavobacterium columnare* strain. The Examiner also maintains that the composition according to Claims 1 and 5 is intended to be used as a vaccine, however the intended use does not impart any critical impact or weight on the physical preparation and the patentability of the product.

Applicants have with the instant response limited the scope of the claimed invention to that set forth in original Claim 2

thereby obviating the rejection of independent Claim 1, as well as dependent Claims 5 and 9.

With the instant amendment, Applicants feel that the basis of all rejections is overcome and allowance of the claims is earnestly solicited. Should the Examiner desire a telephonic interview for the purpose of resolving any perceived issues, Applicants would be most willing to comply.


Respectfully submitted,

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202/720-2421



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